IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE: ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327** **JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**
THIS DOCUMENT RELATES TO: **WAVE 3 CASES LISTED IN EXHIBIT A TO DEFENDANTS' MOTION**	

MEMORANDUM IN SUPPORT OF MOTION TO EXCLUDE GENERAL-CAUSATION OPINION TESTIMONY OF KONSTANTIN WALMSLEY, M.D.

Plaintiffs have identified Konstantin Walmsley, M.D. as their general-causation expert. Although Dr. Walmsley's two general-causation opinions are separately set forth in each of the seven Rule 26 reports for the plaintiffs listed in Exhibit A, the opinions are essentially identical, often verbatim, and are generally confined to the adequacy of the Instructions for Use (IFU) for the TVT, TVT-O, and TVT-Secur products. If permitted, he will testify that IFUs did not reference certain conditions and therefore were "not sufficient to enable informed consent from the patient." Exs. B (Baker), C (Berry) at 7-9, D (Booher) at 4-6, E (Ludwig) at 4-6, F (Mattingly) at 4-6, G (Phillips), H (Ward), Walmsley Reports, Gen. Op. 1.[1] Second, he claims that Plaintiffs were unable to receive "proper informed consent" because the IFUs did not inform

[1] Dr. Walmsley's Rule 26 reports in *Baker*, *Phillips*, and *Ward* contain no page numbers, but the first two opinions in each of the reports in the seven cases at issue are his general opinions, and are labeled as such (General Opinion No. 1 and No. 2) in his reports.

of what Dr. Walmsley claims are safer alternative nonmesh procedures. *See, e.g.*, Exs. B, C at 9, D at 6, E at 6, F at 6, G, H, Walmsley Reports, Gen. Op. 2. Defendants Ethicon, Inc., Johnson & Johnson, and, if applicable, Ethicon LLC (Ethicon) ask that these opinions be excluded for the same reason that this Court excluded an almost identical opinion offered by Dr. Walmsley in the Wave 1 cases: he did not possess then, and still does not possess, the "additional expertise" to opine about what information should or should not be included in an IFU. Ex. I, *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, 8/25/16 Mem. Op. & Order (Walmsley Order), MDL ECF No. 2652 at 6.

To the extent General Opinion No. 2 can be construed to also contain an opinion that safer alternative procedures existed to support a claim for design defect, that opinion too should be excluded as irrelevant or, at the very least, reserved for ruling until trial.[2]

ARGUMENTS AND AUTHORITIES

Ethicon incorporates by reference the standard for *Daubert* motions articulated by this Court in *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

I. Dr. Walmsley does not possess the required additional expertise to offer opinions on what should be included in the IFUs.

In General Opinion No. 1, Dr. Walmsley addresses the sufficiency of the IFU for the TVT products to enable informed consent to be given to the patient. Dr. Walmsley will testify that these IFUs do not include various risks, including contraction, dyspareunia, mesh shrinkage, scar-plate formation, or difficulty removing the mesh if needed, which he claims makes informed

[2] Depositions related to Dr. Walmsley's opinions contained in his Wave 3 reports, including General Opinion No. 1 and No. 2, are still being scheduled in some of the cases listed in Exhibit A. Ethicon reserves the right to supplement this Motion and Memorandum in Support after depositions are taken.

consent impossible. *See* Exs. B, C at 8-9, D at 5-6, E at 5-6, F at 5-6, G, H, Walmsley Reports, Gen. Op. 1. Similarly, in General Opinion No. 2, Dr. Walmsley offers the opinion that the IFUs should have informed of allegedly "[s]afer alternative designs and procedures" that existed at the time. Exs. B, C at 9, D at 6, E at 6, F at 6, G, H, Walmsley Reports, Gen. Op. 2. According to Dr. Walmsley, these "safer alternatives"—*i.e.*, autologous fascial slings—should have been included in the IFUs and without that information, the plaintiff "was unable to receive proper informed consent . . . ." *Id*.

Both opinions should be excluded as Dr. Walmsley is not qualified to offer them. As this Court has previously noted, although an expert who is a urologist or urogynecologist may testify as to the perceived risks to patients associated with the mesh product at issue and whether the IFU at issue conveyed those risks, he "must possess *additional expertise* to offer expert testimony about what information should or should not be included in an IFU." Ex. I, Walmsley Order at 6 (emphasis added); *see Wise v. C.R. Bard, Inc.*, No. 2:12-cv-1378, 2015 WL 521202, at *14 (S.D.W. Va. Feb. 7, 2015). This additional expertise includes experience with product labeling requirements, *Wise*, 2015 WL 521202, at *14, and the development of warning labels, Ex. I, Walmsley Order at 6; *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767, at *4 (S.D.W. Va. Aug. 26, 2016) (excluding Dr. Blaivas's warnings opinions because he "is not an expert in the development of warning labels and thus is not qualified to offer expert testimony about warnings.").

Here, General Opinion No. 1 is identical to the one offered by Dr. Walmsley in the Wave 1 cases, which was excluded by this Court on the basis that Dr. Walmsley "does not possess the additional expertise to offer expert testimony about what an IFU should or should not include." Ex. I, Walmsley Order at 6. His General Opinion No. 2 similarly offers an opinion as to

additional information that should have been included in the IFU for the TVT products. Exs. B, C at 9, D at 6, E at 6, F at 6, G, H, Walmsley Reports, Gen. Op. 2. Although Dr. Walmsley is a practicing urologist, he has no demonstrated expertise related to product labeling requirements or the development of warning labels. In depositions taken in these Wave 3 cases, Dr. Walmsley admitted that he has never consulted with a device manufacturer as to the information to be included in an IFU, has never written or been asked to write an IFU, has never been asked to review an IFU for the United States Food and Drug Administration (FDA), and does not consider himself to be an expert in FDA medical device labeling requirements. *See* Ex. J, Walmsley 8/11/16 Dep. Tr. (Baker) 64:17-24; Ex. K, Walmsley 8/11/16 Dep. Tr. (Ward) 112:8-21. Accordingly, he is not qualified to offer either General Opinion No. 1 or 2 and this testimony should therefore be excluded.

II. The Court should exclude Dr. Walmsley's safer-alternative procedures opinions as irrelevant, or at the very least, reserve ruling.

As demonstrated above, Dr. Walmsley's opinion regarding the availability of "alternative successful and safer sling procedures" at the time of the Plaintiffs' implant surgeries is related to his opinions regarding what should be included in the respective TVT products' IFUs. *Supra* at 3. To the extent, however, that General Opinion No. 2 can be construed to offer an opinion that safer alternative surgical *procedures* existed to treat stress urinary incontinence other than the TVT products, this opinion should be excluded. This is so because the autologous fascial sling—the alternative he proposes to the TVT, the TVT-O, and the TVT-Secur—is a *surgical procedure* and not a *medical device* (*see* Ex. L, Walmsley 8/17/16 Dep. Tr. (Phillips) 53:12-18), and evidence of an alternative surgical procedure cannot support a claim that an implantable medical device is defective in design as a matter of law, and therefore is not relevant to *any* of these individual cases. *Talley v. Danek Med., Inc.*, 179 F.3d 154, 162 (4th Cir. 1999) (rejecting

plaintiff's theory that defendant's spinal-fixation device was defective because there were alternative spinal-fusion procedures available that did not use spinal-fixation devices); *Bogle v. Sofamor Danek Grp., Inc.*, No. 95-8646, 1999 WL 1132313, at *4 (S.D. Fla. Apr. 9, 1999) (emphasizing that the expert's "testimony fails to identify any particular defect *with the product*. He testified that the design of the screw made it difficult to utilize, that only the most skilled surgeons could implant it with any degree of success, that if he were designing a pedicle screw he would design it differently . . . . The Court is not persuaded that such testimony identifies a defect in the product, rather, at the most it identifies that it is a product reserved to a top-rate surgeon" (emphasis added)); *Sita v. Danek Med., Inc.*, 43 F. Supp. 2d 245, 256 (E.D.N.Y. 1999) (granting summary judgment on design-defect claim where expert focused on surgical technique and non-instrumental spinal repair, not a defect in the product itself); *Schmidt v. C.R. Bard, Inc.*, No. 2:11-cv-00978, 2013 WL 3802804, at *2 (D. Nev. July 22, 2013) (granting summary judgment to defendant because "[t]he fact that an alternative method of surgical hernia repair was potentially available does not support[] Plaintiff'[s] design defect claim").

Ethicon acknowledges, however, that this Court has generally reserved ruling on whether an expert's "safer-alternative procedure" opinion is relevant to a claim for design defect, preferring instead to address the relevancy of this opinion in the individual cases and in context during trial. *See, e.g., In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500765, at *3 (S.D.W. Va. Aug. 26, 2016) (Dr. Rosenzweig); *In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500766, at *4 (S.D.W. Va. Aug. 26, 2016) (Dr. Elliott); *In re Ethicon Inc.*, 2016 WL 4500767, at *2 (Dr. Blaivas). If the Court does not exclude Dr. Walmsley's safer-alternatives opinions as irrelevant, it should at least reserve ruling until this issue can be addressed on a case-by-case basis.

CONCLUSION

For the foregoing reasons, Dr. Walmsley's general-causation opinions—General Opinions No. 1 and 2 in these cases—should be excluded in their entirety. Further, to the extent General Opinion No. 2 is construed to support a claim for design defect, it too should be excluded or at least reserved for ruling on a case-by-case basis in each individual case.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on September 19, 2016, I electronically filed this document with the clerk of the court using the CM/ECF system, which will send notification of this filing to CM/ECF participants registered to receive service in this MDL.

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